2020 PANCREATIC CANCER ACTION NETWORK
TRANSLATIONAL RESEARCH GRANT

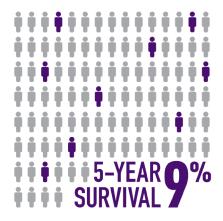Program Guidelines and Application Instructions

PANCREATIC CANCER ACTION NETWORK®

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Please direct questions to:

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grants@pancan.org or (202) 772-3117

PANCREATIC CANCER HAS THE LOWEST FIVE-YEAR RELATIVE SURVIVAL RATE OF ALL MAJOR CANCERS

5-YEAR SURVIVAL 9%

ADVANCE RESEARCH.
SUPPORT PATIENTS.
CREATE HOPE.

I. PROGRAM GUIDELINES

BACKGROUND

The Pancreatic Cancer Action Network's (PanCAN) competitive Grants Program funds promising and meritorious research on pancreatic cancer. The organization's grantmaking strategy recognizes the need to maintain a pipeline of researchers dedicated to studying pancreatic cancer and acknowledges an urgency to accelerate scientific and medical breakthroughs that benefit patients. Early career grants are awarded to attract researchers to the field of pancreatic cancer, and translational and clinical grants support research that is well positioned for next steps and has the potential to drive improvements in clinical practice and patient outcomes. In 2014, PanCAN launched a grant mechanism to fund translational research. Since then, 27 translational research projects have been funded through these grants.

Grant recipients not only receive financial support for their funded research, but also join the *Community for Progress,* built by PanCAN. The *Community for Progress* is a growing, robust and collaborative research community that is dedicated to changing the course of history for pancreatic cancer.

GRANT SUMMARY

The 2020 Pancreatic Cancer Action Network Translational Research Grant will fund high priority pancreatic cancer research that is poised for important translational next steps to help move scientific discovery to application in patients. **PanCAN has partnered with the Celgene Corporation** to accelerate the development of novel therapies by establishing strong relationships between academia and industry through research grants. Funded projects will benefit from industry input and insight, leading to an accelerated translation into a therapeutic product. The grant provides $500,000 over two years, with the potential to expand to a third year with additional funds. Projects will be strategically supported by both PanCAN and Celgene to facilitate progress and increase the likelihood of success.

To be eligible for a Translational Research Grant, **the research project should aim to identify novel targets and approaches to the <u>treatment</u> of pancreatic cancer or understand and circumvent treatment resistance.** Of particular interest are research projects that fall into at least one of these three areas of research: a) Immune context and tumor microenvironment interactions, (b) Regulators of pathogenesis, progression and metabolism, with particular interest in epigenetic mechanisms and (c) Transcriptional networks essential for viability and maintenance of malignant phenotype.

It is anticipated that four Translational Research Grants will be awarded.

IMPORTANT DATES

- Applications are due on December 6, 2019, by midnight Eastern Standard Time.
- Funding decisions are anticipated by May 2020.
- Start of grant term is July 1, 2020.
- Grant recipients are expected to attend PanCAN's Annual Scientific Summit. Exact dates and location are to be determined.

APPLICANT ELIGIBILITY

- Applicants must have a doctoral degree (including PhD, MD, DO, DC, ND, DDS, DVM, ScD, DNS, PharmD or equivalent) in the biomedical sciences or in a field applicable to health science research and not currently be a candidate for a further doctoral degree.
- The contact principal investigator (contact PI) must be affiliated with an accredited academic, medical or research institution. International institutions are included.
- One co-PI may be named. The co-PI should be affiliated with any academic, medical or research institution, including international institutions. The co-PI must have a doctoral degree. Researchers can be a contact PI on one application and may be identified as a co-PI on a second application.
- Employees or subcontractors of a government entity are not eligible to be a PI or to receive funds from the grant, but can be included as a collaborator or project investigator.

STUDY SCOPE AND PROJECT TOPICS

Projects should be built on a strong foundation of basic research and propose steps that translate that finding into a drug or immunologic approach to the treatment of pancreatic cancer. The intent of the project should be to extensively validate novel targets and/or identify novel approaches to the treatment of pancreatic cancer or understand and circumvent treatment resistance. Translational research involving robust animal models is permitted but there is emphasis on the incorporation of human tumors or tumor-derived tissue. There is particular interest in co-development of a biomarker that can be used to identify a subset of pancreatic cancer patients most likely to respond to the proposed therapeutic intervention. **Projects should not include proprietary compounds for which the PI or institution does not control intellectual property rights.** It is recognized that translation into clinical testing is unlikely to be feasible within the scope of these projects. The project term is two years; however, contingent on success, projects may be expanded to a third year (determined separately from this application).

Application projects are limited to the following:

1. The study of a molecular treatment or approach but not a device or surgical intervention.

2. A molecular treatment or approach that is novel and within the intellectual property rights of the applicant's institution. Combination treatments that are dependent on proprietary compounds outside the control of the applicant are not permitted.

3. Studies that fall into at least one of these **three areas of interest**:

   - Immune context and tumor microenvironment interactions.

   - Regulators of pathogenesis, progression and metabolism, with particular interest in epigenetic mechanisms.

   - Transcriptional networks essential for viability and maintenance of malignant phenotype.

The following are examples of projects that fall within the project scope of the 2020 Translational Research Grant. **Please note that these are examples, and proposals are not restricted to these specific projects.**

- In-depth studies to understand the impact of disrupting a molecular mechanism that regulates a component of the immune response (e.g., T-cell exclusion) in a genetically-engineered mouse model of pancreatic cancer with supporting data from human pathological specimens.
- Molecular mechanisms underlying the role of factors produced by supporting cells, such as macrophages, myeloid-derived suppressor cells and/or fibroblasts, in paracrine support of tumor epithelial cell proliferation using complex modeling systems (e.g., human tumor-derived cells in organotypic models).
- Studies to understand short- and long-term effects of disrupting the activity of a chromatin remodeling enzyme or a Zn-finger transcription factor on tumor cell proliferation and metabolism in molecularly characterized patient-derived xenografts (or other complex model systems).
- Studies in murine or human tumors testing the impact of disrupting transcriptional nodes identified by previous bioinformatics.

USE OF FUNDS

The Translational Research Grant provides $500,000 over two years. Funds can be used for salaries and benefits, laboratory supplies, equipment (maximum of 10 percent of total grant), subject trial costs and publication charges for manuscripts that pertain directly to the proposed project. Expenses for regular communications can be included if a co-PI is located at a different institution.

For institutions that mandate payment of indirect costs, **a maximum of 10 percent** of the total grant may be used for this purpose across all institutions. Any general office supplies or individual institutional administrative charges (e.g., telephone, other electronic communication, utilities, IT network, etc.) are considered to be part of indirect expenses and are not allowable budget line items.

Professional membership dues, pre-award charges and any other research-related expenses not directly related to the project are not allowable expenses. In addition, no grant funds may be directed toward salary or benefits of any individuals from a government or for-profit entity, or for any research expenses related to the project that are incurred by these individuals.

SPECIAL CONSIDERATION

Please be advised that the Celgene Corporation will be involved with the funded project, will have access to project results such as progress reports and will have first negotiation rights for further project development. Further, publishable manuscripts that result from funded projects are subject to editorial review by Celgene. If the applicant believes that this creates a conflict or for further information, please contact grants@pancan.org **before** applying.

The applicant is required to share the contents of the Grant Terms and Conditions with their relevant Contracts and Grants and/or Technology Transfer departments (see below for details on how to download this document from the proposalCENTRAL site and upload the required signature) to avoid issues with Intellectual Property and/or first negotiation rights.

EVALUATION OF APPLICATIONS

The 2020 Translational Research Grants will be awarded using a competitive, rigorous peer-review process. Applications will be evaluated by a scientific review committee composed of scientists from academia and industry who are respected for their accomplishments in pancreatic cancer, translational research and clinical trials. A pancreatic cancer research advocate will also serve on the committee to represent the collective patient perspective. **The Celgene Corporation will not be involved in the review and selection process and will not have access to applications until they are funded.**

The Committee will consider the following criteria when reviewing applications:

- *Merit and scope:*
    - Is there is a strong scientific rationale for the proposed project?
    - Are there sufficient background and preliminary data to support the relevance of the proposed project?
    - How well does the proposed research conform to the intent, scope and areas of interest identified for this grant mechanism?

- *Translational potential and feasibility:*
    - Does the proposed project address a high priority or novel translational research area that challenges and seeks to shift current clinical practice paradigms?
    - Is the proposed project based on a plan that is well reasoned, realistic and feasible?
    - Have possible barriers been anticipated and are solutions and alternative strategies proposed?
    - Are all the needed resources, including drugs and reagents, readily available?
    - Are proposed expenses fully justified and reasonable in relation to the proposed project?

- *Outcomes:*
    - Are quantifiable milestones and deliverables clearly specified and reasonable?
    - Is there a plan to measure project outcomes, and is it reasonable and appropriate?

- *Project team:*
    - Does the PI(s) have the appropriate training, expertise and track record of accomplishments to successfully implement the proposed project and overcome obstacles that may arise?
    - Do the project team members have the needed cross-disciplinary skills and capabilities to successfully complete the project, and is there evidence that they can successfully work together?
    - Has the necessary infrastructure for the project been identified, and is the environment appropriate and conducive to the success of the project?
    - If the project involves multiple institutions, is the communication plan sufficient?

II. APPLICATION INSTRUCTIONS

Applications are due by **midnight** Eastern Standard Time on Friday, December 6, 2019, using the proposalCENTRAL website at https://proposalcentral.com.

In order to submit an application, applicants need to enter information directly into the online submission platform as well as upload a number of documents. The following instructions provide details about information that needs to be entered and the materials that need to be uploaded. The section numbering in the table below corresponds to the application sections found on the left side of the proposalCENTRAL application webpage and to the sections that follow in the Application Instructions.

Information to be entered directly into proposalCENTRAL	*Instructions/ proposalCENTRAL Section*
Title Page	1. Title Page
Enable Other Users to Access this Proposal (optional)	3. Enable Other Users to Access this Proposal
Contact PI (Applicant) Information	4. Applicant
Institution and Contacts	5. Institution and Contacts
Project team	6. Project team
Scientific Abstract	7. Scientific Abstract
Budget	8. Budget
Budget Summary and Justification	9. Budget Summary and Justification
Secured and Pending Support	10. Secured and Pending Support
Organizational Assurances	11. Organizational Assurances
Templates to be downloaded, completed and uploaded	
Download templates:	
• Project Proposal Template	
• Project Milestones and Timeline Template	
• Grant Agreement Terms and Conditions	
• Patent and Intellectual Property Agreement	2. Download Templates and Instructions
Upload documents:	
• Project Proposal (eight-page project narrative)	
• Project Milestones and Timeline	
• Biographical Sketch(es)	
• Letter(s) of Institutional Support	
• Letter of commitment from the co-PI	
• Letter(s) of commitment from collaborator(s)	
• Signed Acknowledgement of Grant Agreement Terms and Conditions	
• Signed Acknowledgement of Patent and Intellectual Property Agreement	
• Application Signature Pages (section 15)	
• Other Materials (optional)	12. Application Documents
Other sections to be completed before submission	
PI Data Sheet	13. PI Data Sheet
Validate	14. Validate
Print Signature Pages and Application	15. Print Signature Pages and Application
Submit	16. Submit

GETTING STARTED IN PROPOSALCENTRAL

If you are a new user of proposalCENTRAL, follow the "REGISTER" link and complete the registration process. After you click the "Create One Now!" button, complete your Professional Profile (fourth tab from the left) before starting an application.

If you are already registered with proposalCENTRAL, access the site and log in with your Username and Password. If you have forgotten your password, click on the "Forgot Your Username/Password?" link. Supply your User ID or email address in the space provided; your password will be sent to you by email.

To start an application, select the "Grant Opportunities" tab (gray tab furthest to the right). A list of applications will be displayed. Find the Pancreatic Cancer Action Network "Translational Research Grant" and click the "Apply Now" link (second-to-last column) to create your application.

Complete all fields in the application and all templates that are provided. Upload all requested documents in portable document format (PDF). For more information, see the proposalCENTRAL FAQ section under the "Help" link at the top right of the page.

*Important note: To ensure your PDF files upload in their entirety, please avoid: replacing files multiple times, using files that were once password-protected or encrypted and combining multiple scanned documents or files into one PDF. Review your full application before submitting to check that all pages of your PDF files are displaying properly.

> *If you have difficulty registering, logging in or creating your application, contact proposalCENTRAL Customer Support. Phone: (800) 875-2562 or (703) 964-5840; Email: pcsupport@altum.com.*

COMPLETING AND SUBMITTING THE APPLICATION

The following information is required to submit a complete application. Numbers correspond to the application sections found on the left side of the proposalCENTRAL application webpage.

1. **Title Page.** Enter the title of the proposed research project directly into the proposalCENTRAL system. The title is limited to no more than 75 characters in length (including spaces). Do not use abbreviations. A project title must be entered and saved before additional sections may be accessed. Also complete the other required (*) items on this page.

2. **Download Template and Instructions.** The Guidelines and Application Instructions document, the Grant Agreement Terms and Conditions, the Patent and Intellectual Property Agreement, the Project Proposal template and the Project Milestones and Timeline template should be downloaded from this page. Click the "Download" icon to save each of the templates to your computer. See below instructions on how to complete the templates.

3. **Enable Other Users to Access this Proposal.** Optional. This feature enables you to initiate one application that all relevant parties can access.

4. **Contact PI (Applicant) Information.** Enter information for the contact PI directly into the proposalCENTRAL system. The contact PI is required to update his/her Professional Profile, including Contact Information, Other Support* and Publications. *The "Other Support" information, including secured and pending support, should be imported into section 10, "Secured and Pending Support" (see below).

5. **Institution and Contacts.** Enter information for the contact PI's institution, post-award contact person and the designated signing official directly into the proposalCENTRAL system.

6. **Project Team.** Enter contact information for the co-PI, if included in the application, directly into proposalCENTRAL. Also enter contact information for investigators and other key personnel that will comprise the project team. Project members should be separately listed for each participating institution beginning with the most senior role.

7. **Scientific Abstract.** Enter the abstract directly into the proposalCENTRAL system. The abstract should be limited to 3,000 characters (including spaces) and must be concise and comprehensive. Describe the relevance of the proposed project to pancreatic cancer, the foundational research that has been completed to justify proposed next steps, the practical application that is planned, the specific aims, activities and study design, expected accomplishments by the conclusion of the grant term and how results will contribute to the goal of improving patient outcomes.

   [NOTE: The proposalCENTRAL system does not lock the scientific abstract field after 3,000 characters have been entered. To ensure that your abstract does not exceed the character limit, click the red "Save" button at the top or bottom of the screen before proceeding to the next section. If the scientific abstract is too long, you will receive an error message at the top of the page.]

   From the list provided, select the primary and, if applicable, secondary Common Scientific Outline code that best describes the proposed project. For additional details about these research categories, see https://www.icrpartnership.org/CSO.

8. **Budget.** The Translational Research Grant provides $500,000 over two years. The Budget should be presented for each year of the grant term ("period"). For each period, please complete:

   - Personnel Costs: Complete Name, Role, Percent Effort, Base Salary, Requested Salary and Requested Fringe. In "Other Role," precisely describe the role the person has on the project.

     No grant funds may be directed toward salary or benefits of any individuals from a U.S. government, nor for any research expenses related to the project that are incurred by these individuals.

   - Non-personnel Costs: Complete Materials and Supplies, Equipment, Travel, Publication and Other Expenses costs. For each category, choose a line item category from the dropdown menu.

     Professional membership dues, pre-award charges and any other research-related expense not directly related to this project are not allowable expenses.

   - Indirect Costs: A maximum of 10 percent of the grant may be used for this purpose. Indirect costs should be part of the total grant amount. No additional funds will be granted for indirect costs.

Any general office supplies or individual institutional administrative charges (e.g., telephone, other electronic communication, utilities, IT network, etc.) are considered to be part of indirect and are not allowable budget line items.

9. **Budget Summary.** This page contains a summary of the proposed Budget completed in section 8. At the bottom of the page, provide a budget narrative in under 5,000 characters that justifies the application budget detailed in section 8. Include subheads for Personnel, Materials and Supplies, Equipment, Travel, Publication and Other Expenses costs.

10. **Secured and Pending Support.** Please add all PI existing (active) and pending support. For each entry, select if there is overlap with this application and, if so, provide a description of the overlap. To add Support entries, please follow the instructions on the page to choose entries from your Professional Profile. If you do not already have Other Support entered in your profile, click the "Edit Professional Profile" button to open your profile and follow the instructions to add entries to this page. Please note that if the grant is awarded, we will request an updated list of support, including for the co-PI.

11. **Organizational Assurances.** Select the appropriate assurances options for your proposed research and complete the Approved or Pending Date field. If a grant is awarded, you will be required to submit the regulatory and compliance documents to the Pancreatic Cancer Action Network.

12. **Application Documents.** Upload all required documents. For instructions and details on the required documents, see "Completing the Application Documents" below.
    - Project Proposal (please see template for page limits, eight pages for Project Narrative)
    - Project Milestones and Timeline
    - Biographical Sketch(es) (of the Applicant and, if applicable, of the co-PI)
    - Letter(s) of Institutional Support (from PI institution and, if applicable, co-PI institution)
    - Letter of commitment from the co-PI
    - Letter(s) of commitment from collaborator(s)
    - Signed Acknowledgement of Grant Agreement Terms and Conditions
    - Signed Patent and Intellectual Property Agreement
    - Application Signature Pages

    To upload the documents, all documents must be converted to PDF files. To ensure your PDF files upload in their entirety, please avoid replacing files multiple times, using files that were once password protected or encrypted and combining multiple scanned documents or files into one PDF. Follow the instructions on the page to upload the documents. In the section for attachments, all the required attachments are listed in the middle of the screen. This list helps you track completion and uploading of your required attachments. Click the "Attach Files" button to upload your documents. Once you upload a required attachment, that attachment type will be removed from the required list and will be displayed in the "Current list of uploaded attachments." If you wish to modify the attached file, make the revisions to your original file on your computer (offline), convert the file to PDF and use the same process above to attach the newly revised file. Delete any previously submitted versions of the file before submitting your application.

13. **Contact PI Data Sheet.** This is an automatically populated data sheet based on the contact PI's proposalCENTRAL profile. Information for gender, race and ethnicity must be provided. If fields are not populated, go to Section 4, Contact PI (Applicant), and select the "Edit Professional Profile" tab in the center of the screen. The contact PI must then go to the column on the left side of the screen, select "4) Personal Data for Application" and enter his/her gender, race and ethnicity. The Scientific Review Committee does not receive this information.

14. **Validate.** Validate the application on proposalCENTRAL. This is an essential step. "Validate" checks for required data and required attachments. You will not be able to submit the application if all the required data and attachments have not been provided.

15. **Print Signature Pages and Application.** After completing all appropriate sections for your application, you may print the Signature Pages by clicking the "Print Signature Pages" button. Note that if information is missing in the Signature Pages, it could be because you have not entered the information in one of the application sections OR because the information is not required for this grant application. If the institution's Employer Identification Number (EIN) is not completed in the Signature Pages, please request your institution to provide the information in their proposalCENTRAL profile. If you wish to view the application in its entirety (recommended), select the "Print Signature Pages and Attached PDF Files" option.

    Obtain required signatures. A signed Signature Pages with the original signatures must be uploaded into Application Documents (see section 12 above). Only upload the Signature Page (not the Application Contacts or Scientific Abstract pages). Signatures transmitted by electronic means shall have the same force as original signatures.

16. **Submit.** After successfully passing the validate check and printing your documents, click the "Submit" link. An email will be sent to you confirming your submission. Once your application is submitted, you may view it by accessing the "Submitted" link under the "Proposals" tab. The status column will show "Submitted" and the date submitted. You may need to refresh your browser screen after submitting the application to see the updated status.

COMPLETING THE APPLICATION DOCUMENTS

- **Project Proposal.** Complete on the template available from section 2 on the proposalCENTRAL application website. Formatting restrictions and detailed instructions for completing the Project Proposal template are indicated in the template. The template indicates page limitations for each section, with an eight-page limit for the Project Narrative.

- **Project Milestones and Timeline.** Complete on the template available from section 2 on the proposalCENTRAL application website. The Project Milestones and Timeline template is meant to list the various milestones and deliverables necessary to complete the research aims and the estimated time it will take to complete each. Detailed instructions are indicated in the template.

- **Biographical Sketch(es).** A biographical sketch should be submitted for the Applicant (PI), and if a co-PI is included in the application, for the co-PI. The biographical sketch must be in English. The NIH Biographical Sketch Form (OMB No. 0925-0001/0002 [Rev. 09/17]) is acceptable. The contact PI must adhere to the five-page page limit and other biographical sketch requirements.

- **Letter(s) of Institutional Support.** One letter should be submitted for the applicant (PI), and if a co-PI is included in the application, an additional letter is required from the co-PI institution. The letter must be written on letterhead by the department head, dean or other senior member of the institution and should be addressed to the Scientific Review Committee. The letter should explain the relationship of the Applicant (PI) or co-PI with the institution, the nature and extent of support for the proposed research that is available from the institution, including laboratory space, financial support and other resources, and confirm that the proposed project will not present a conflict of interest with the PI's or co-PI's other responsibilities and commitments.

- **Letter of commitment from the co-PI.** Required if a co-PI is included in the application. The letter should confirm the scope of the co-PI's involvement in the proposed project, including the percent effort, and be addressed to the Scientific Review Committee.

- **Letter(s) of commitment from collaborator(s).** A Letter of Commitment is required from all collaborators, including drug or agent suppliers, other organizations providing materials or data and collaborating investigators. The letter should clearly state the specific commitment of the collaborator, whether the involvement is contingent

on any factors and the timing of the involvement. The letter should be written on letterhead by the signing institution or company and should be addressed to the Scientific Review Committee.

- **Signed Acknowledgement of Grant Agreement Terms and Conditions.** To ensure that the appropriate parties are informed of the terms and conditions of the grant, a copy of the Grant Agreement Terms and Conditions must be downloaded from Section 2 of the proposalCENTRAL application webpage. The final page of the document must be signed by the contact PI and sponsoring institution, indicating that they have read the document. **This is not a legally binding document. If an application is funded, the terms and conditions may be negotiated. We do not negotiate the terms in the application stage. However, if specific sections are in conflict with the institution policies, please contact the grants department.** A scanned copy of the signed page must be uploaded into the online application in the section for attaching files.

- **Signed Patent and Intellectual Property Agreement.** To ensure that the appropriate parties are informed of the Patent and Intellectual Property stipulations of this grant, a copy of the Patent and Intellectual Property Agreement must be downloaded from Section 2 of the proposalCENTRAL application webpage. The final page of the document must be signed by the contact PI and sponsoring institution, indicating that they have read the document. A scanned copy of the signed page must be uploaded into the online application in the section for attaching files.

- **Application Signature Pages.** In order to ensure the appropriate parties have approved the application, the signature pages, as described in Section 15 above, must be printed and signed. The signed signature page (with original signatures from the contact PI and institution's signing official) must then be scanned and uploaded into the online application in the section for attaching files. Signatures that are electronically transmitted shall have the same force and effect as original signatures.

CHANGING YOUR APPLICATION

Withdrawal of application. Please advise PanCAN promptly, in writing, should you decide to withdraw your application. Your email (or letter) should include your name, the title of the proposal and the reason for withdrawal.

Change of address. Notify PanCAN in writing of any changes of address, email or phone number, following the submission of an application. Include your name and the application number.

Change of institution or position. If you change your institution or professional position, contact PanCAN to determine whether your application is still eligible for funding consideration.

INQUIRIES

Inquiries or technical issues regarding proposalCENTRAL and the online application process should be directed to customer support at (703) 964-5840 or toll-free at (800) 875-2562 or by email at pcsupport@altum.com.

Inquiries about the 2019 Translational Research Grant guidelines and application materials should be directed to grants@pancan.org or (202) 772-3117. Contact person: Valerie Holzherr, Manager, Research and Grants.

PANCREATIC CANCER ACTION NETWORK

THE PANCREATIC CANCER ACTION NETWORK is dedicated to fighting the world's toughest cancer. In our urgent mission to save lives, we attack pancreatic cancer on all fronts: research, clinical initiatives, patient services and advocacy. Our effort is amplified by a nationwide network of grassroots support. We are determined to improve patient outcomes today and to double pancreatic cancer survival.